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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890
26259	7590	03/26/2004		
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER CHATTOPADHYAY, URMI	
			ART UNIT 3738	PAPER NUMBER 19
DATE MAILED: 03/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,641

Applicant(s)

LAURENCIN ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. The Request for Reconsideration filed 1/26/04 has been entered as Paper No. 18.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hlavacek et al. (USPN 4,792,336 as cited in applicant's IDS) in view of Chervitz (USPN 4,917,699 as cited in previous office action).

Hlavacek et al. discloses a ligament or tendon implant with all the elements of claim 1, but is silent to the braided scaffold being a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique. See column 3, lines 56-60 for a tendon or ligament replacement construct comprising a porous (column 6, lines 51-53), degradable and polymeric fiber-based (column 4, lines 57-65) scaffold (column 1, lines 11-14) that is braided (column 5, lines 13-14). See column 8, lines 55-59 for a method of replacing a damaged ligament in a patient (claim 6). Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the

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optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 2, lines 43-49 and column 3, lines 1-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Chervitz to modify the flat braid scaffold of Hlavacek to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 1, lines 26-32 and 43-50.

4. Claims 2-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hlavacek et al. in view of Chervitz, and further in view of Vacanti (USPN 5,855,610 as cited in previous office action).

Hlavacek et al., as modified by Chervitz, discloses a ligament or tendon implant with all the elements of claims 1 and 2, but is silent to scaffold being seeded with cells, ingrowth of which is supported by the scaffold, as required by claim 2, and the method for producing a graft material comprised of living cells in a biodegradable matrix and respective steps, as required by claim 8. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, porous scaffold (see abstract, column 3, lines 41-60, column 4, lines 1-25) seeded with cells (column 2, lines 52-53), ingrowth of which is supported by the scaffold (column 3, lines 22-23). Examiner contends that seeding the scaffold with cells, specifically *in vitro*, provides for a more rapid development and differentiation process for the tissue being formed,

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and it is clear that cellular differentiation and the creation of tissue specific extracellular matrix is critical for the engineering of a functional implant. Seeding cells onto the scaffold prior to implantation also provides the scaffold with greater strength when the cells proliferate, which allows for the scaffold to endure the *in vivo* forces that act upon it once implanted. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vacanti et al. to modify the ligament implant of Hlavacek et al. and Chervitz, following the method of Vacanti, by seeding the polymeric scaffold with cells in order for a more rapid development and differentiation process of the tissue being formed and added strength to the scaffold prior to implantation.

Vacanti et al. also teaches the limitations of claims 3-5 and 9-11, which require the cells be mesenchymal in origin, generate mesenchymal cells and be pluripotent stem cells, respectively. See column 6, lines 35-40 and 50-53. It would have been obvious to one of ordinary skill in the art to modify the implant of Hlavacek et al. and Chervitz by seeding the scaffold with cells that are mesenchymal in origin, say fibroblasts, in order to form a ligament replacement construct or with pluripotent stem cells because they are immunologically inert.

Claim 7, see column 8, lines 55-59 for Hlavacek et al. disclosing the method of replacing a damaged ligament.

Response to Arguments

5. Applicant's arguments filed 1/26/04 have been fully considered but they are not persuasive. Applicant argues that in contrast to applicant's invention of degradable, porous, polymeric fibers, the fibers of Chervitz are ultra high weight polyethylene fibers, which are some

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of the strongest, most resilient polymers known. Due the mechanical forces involved in the three dimensional braiding process and the differences in the mechanical properties of the degradable fibers versus fibers taught by Chervitz, the teaching of Chervitz is in no way predictive of successfully producing a three dimensional braided scaffold of degradable polymeric fibers.

6. The examiner disagrees; there is a reasonable expectation of success. Each of applicant's independent claims are "open" by using "comprising". This means that the replacement construct is not limited only to degradable, porous, polymeric fibers and can include other elements. In column 4, lines 62-65, Hlavacek et al. discloses that the device has an absorbable component comprising from about 10 to 100 percent of polymer having a glycolic or lactic acid ester linkage and that the remainder of the device has a nonabsorbable component. In column 6, lines 30-34, the nonabsorbable component is disclosed as including high strength/modulus polyethylene. In an embodiment wherein the absorbable component of Hlavacek et al. is 10 percent of polymer having a glycolic or lactic acid ester linkage and the remaining nonabsorbable component is of high strength/modulus polyethylene, the device would be much stronger than if the device were made from 100 percent of polymer having a glycolic or lactic acid ester linkage and no nonabsorbable component of high strength/modulus polyethylene. When the three dimensional braiding technique of Chervitz is applied to this stronger device embodiment, there is a reasonable expectation of success in producing a three dimensional braided scaffold that includes degradable polymeric fibers. No evidence has been provided to prove otherwise.

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Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.


Urmi Chattopadhyay

Art Unit 3738


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